

Appl. No. 09/626,366
Docket No.: D4857-00006
Reply to Office Action of October 22, 2003

REMARKS/ARGUMENTS

As a result of this Response, claims 1 - 17 are under active consideration in the subject patent application.

In the Official Action, the Examiner has:

- (1) acknowledged the Request for Continuing Examination and withdrawn the finality of the Final Office Action;
- (2) rejected claims 1 - 17 under 35 U.S.C. § 103(a) in view of a combination of U.S. Patent No. 6,370,511, issued to Dang (the "Dang reference"), U.S. Patent No. 6,277,071, issued to Hennessy et al. (the "Hennessy reference"), and U.S. Patent No. 6,077,082, issued to Gibson et al. (the "Gibson reference"); and

- (3) cited prior art that is made of record but not relied upon.

With regard to Item 1, no further comment appears necessary.

With regard to Item 2, Applicant respectfully traverses the Examiner's proposed combination of the Dang and Hennessy references with the disclosure of the Gibson reference, and requests reconsideration and withdrawal of the rejection of claims 1-17 under 35 U.S.C. §103 for the following reasons.

The Examiner continues to rely, inappropriately, upon the Dang and Hennessy references in support of the rejection of claims 1 - 17. Contrary to the Examiner's statement at page 4, paragraph (B) no motivation is provided within the Dang and Hennessy references, taken as a whole, to support their combination with one another, nor has the Examiner established that such

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motivation to combine exists. In order for a *prima facie* case of obviousness to be established, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, and the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2142. The Examiner is required under the rules to (i) identify such motivating disclosure, or (ii) the knowledge generally available to one of ordinary skill in the art to support the proposed combination. Contrary to the Examiner's comments at paragraph (B), the Examiner has failed to provide either (i) or (ii) in paragraph (A).

The primary objective of the present invention is to provide a process for accessing and documenting wound and skin conditions that includes an automatically triggered alerting mechanism that is activated, in real time, when a treatment is initiated on a living, breathing patient by a treating physician, which treatment deviates from an expected or standard treatment under the then current clinical circumstances. Neither Dang nor Hennessy alone or in any valid combination provide or suggest such a methodology, and neither provide the requisite motivation to combine them as the Examiner has done, absent impermissible hindsight.

The Examiner has admitted that Dang and Hennessy do not collectively disclose issuing an alert notice to a clinician at the time of performance of an identified clinical action identified as a variance from the identified appropriate

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clinical pathway so as to allow the clinician to alter the clinical action. Thus, the Examiner admits that claims 1 - 17 are patentable over the combined teachings of Dang and Hennessy. The Examiner states that such a feature (i.e., the issuance of an alert notice) is known in the art as evidenced by the Gibson reference, and that motivation exists within Gibson to support its combination with the collective teachings of Dang and Hennessy. Applicant respectfully submits that the Examiner's position cannot be supported, in any way, by the teachings of the Gibson reference.

Unlike Applicant's invention, the invention of the Gibson patent seeks to provide a patient simulation system providing an image of a body of a patient on a computer display for use by medical students. A communication device is provided to allow interaction between the image of the patient and a user, and a behavior generator (i.e., simulation software) causes the image of the patient to appear to respond to treatment, e.g., administration of medication, surgical procedures, etc. The simulation software is designed to pose questions to the user, simulate the bedside manner of the user, and various therapies. Devices for facilitating communication between the student-user and the image of the patient are suggested by Gibson, including *voice synthesizers for allowing verbal interaction, computer input/output devices such as a keyboard, mouse, joystick, track ball, pressure sensitive pad and the like, and a device for activating a pager system.*

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Gibson is not directed at providing a method or system for assessing deviations from pre-selected medical treatments as are all of Applicant's claims. Instead, Gibson is directed to providing a simulation software package that mimics an actual clinician-to-patient interaction. Gibson is not directed at solving the particular problem being solved by the instant invention, i.e., assessing deviations from a preselected medical treatment, and Gibson never once suggests that they are assessing the users choices for clinical action. Significantly, Gibson does not teach or suggest issuing an "alert notice" or alarm of any kind. In fact, a computer-aided keyword search of the entire Gibson reference demonstrates that Gibson never once uses the words "alert" or "notice"!

The Examiner first identifies col. 1, lines 22 - 51, in support of the allegation that Gibson discloses "issuing an alert notice to a clinician". At col. 1, lines 22 - 51, after describing the basic elements of the simulation system, Gibson states as follows:

"... Devices for facilitating communication between the user and the patient include voice synthesizers for allowing verbal interaction, computer input/output devices such as a keyboard, mouse, joystick, track ball, pressure sensitive pad and the like, and a device for activating a pager system. Further, the behavior generator is programmed to cause the patient to appear to respond to the administration of medication, surgical procedures, questions posed by the user, the bedside manner of the user and various therapies. . . Known simulations do not represent physical and psychological patient reactions. However, such reactions are a significant part of actual medical practice. Further, significant portions of the doctor-patient relationship such as the possibility of the patient requiring attention at any particular moment of the day, false responses and symptoms, and response to bedside manner are provided by the present invention for a more realistic experience than known simulations. [emphasis added]

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Nothing in this passage even vaguely suggests that an "alert notice" is to be given, and not one of the devices named by Gibson as provided for facilitating communications between the user and the patient is capable of providing an "alert notice" to a clinician at the time of performance of a clinical action. The Examiner is reminded that Gibson's voice synthesizer is for allowing verbal interaction with the virtual patient, not for alerting the student-user to possible variances from preferred clinical pathways. Furthermore, the knowledge generally available to one of ordinary skill in the art would say that *computer input/output devices such as a keyboard, mouse, joystick, track ball, pressure sensitive pad and the like* do not, expressly or inherently, teach or suggest the issuance of an alert notice of the type and for the purpose defined by Applicant's claims. The device for activating a pager system contemplated by Gibson does not issue an alert, and no such function is taught or suggested by Gibson. In fact, Gibson actually teaches away from such a possibility.

The Examiner has apparently overlooked Gibson's own description of how the simulation will operate in connection with a pager system (col. 4, lines 20 – 42). Applicant respectfully submits that if, as the Examiner has stated, Gibson suggests issuing an alert notice (via his pager system) to a clinician at the time of performance of the identified clinical action, then why would Gibson advocate as an example of the simulation invention, at col. 4, lines 25 - 29:

"...Practicing physicians cannot simply "pause" the action when they become fatigued, otherwise involved, distracted or frustrated. Further, instant

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responses to medical treatments are not always observable in actual medical practice. Hence, these difficulties are mimicked in the simulation by, for example, *forcing the user to wait some period of time up to hours, days or weeks to get results from ordered tests. . .*[emphasis added]

Of all of the communication devices suggested by Gibson, only the pager system would appear capable of the foregoing operational functionality. Yet, Gibson states that "instant responses to medical treatments" are not always observable, and constitute a difficulty. If Gibson were concerned at all with assessing clinical actions and alerting a clinician at the time of performance, of a variance from an identified appropriate clinical pathway, Gibson would not teach an example of operation of the system where the ability to page (alert?) a student is some period of time up to hours, days or weeks after performance of the clinical action; nor would Gibson suggest that "instant responses" (such as an "alert notice") constitute a difficulty!

The invention of the Gibson patent is within the field of medical education software for generating computer-based simulations of medical procedures directed at students (Col. 1, lines 10-11). This is clearly not the same problem being solved by Applicant. There is nothing in the disclosures of Dang, Hennessy, or Gibson collectively which is remotely related to either (i) accessing and documenting wound and skin conditions; or (ii) automatically triggering an alerting mechanism that is activated, in real time, when a treatment is initiated on a living, breathing patient by a treating physician, which treatment deviates from an expected or standard treatment under the then current clinical circumstances. In fact, Gibson suggests that ". . . *some period of time up to hours, days or weeks.*

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..." may lapse after performance of the clinical action to notify the student-clinician.

In light of the absence of any motivation to use the clinician-patient interaction simulation software disclosed in the Gibson patent with the methods taught in the Dang and Hennessy references, Applicant submits that the Examiner's combination of references is improper. For at least the above reasons, Applicant submits that the combined teachings of the Dang, Hennessy, and Gibson references are not properly combinable. Indeed, it appears that the Examiner has again used hindsight reconstruction to piece together teachings of the prior art to render the invention of claims 1-17 obvious under 35 U.S.C. §103. The Examiner is reminded that the Federal Circuit has previously stated that the "prior art may not be gathered with the claimed invention in mind" and that the use of "hindsight reconstruction to pick and choose among isolated disclosures" is impermissible.

Accordingly, claims 1 - 17 are patentable over the Dang and Hennessy references collectively, and over the invalid combination of their teachings with that of Gibson. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103 are respectfully requested.

With regard to Item 3, Applicant has considered the prior art references identified by the Examiner as pertinent and determined that none of them, alone, or in any valid combination with the Dang, Hennessy or Gibson references anticipates or renders obvious the present invention.

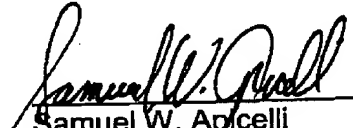
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In view of the foregoing, Applicant respectfully submits that claims 1-17 are in condition for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If a telephone conference would be of assistance in advancing prosecution of the above-identified application, Applicant's undersigned Attorney invites the Examiner to telephone him at 717-237-5516.

Respectfully Submitted,

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